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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,715	05/12/2005	Takanori Uchida	UCHIda7	6851

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EXAMINER	
KIM, TAEYOON	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,715	UCHIDA ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending.

Response to Amendment

Applicant's amendment and response filed on Feb. 16, 2007 has been received and entered into the case.

Claims 10-16 have been newly added, claims 1-16 are pending and have been considered on the merits. All arguments have been fully considered.

Terminal Disclaimer

The terminal disclaimer filed on Feb. 16, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/542577 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

Applicant argued that the reference (Greenawalt et al.) does not teach the use of a material in the form of nonwoven fabric. The examiner respectfully disagrees with the assertion. Greenawalt et al. teach a material made by a method of collecting the fibrous pulp uses forming fabric. Although Greenawalt et al. is silent whether the fibrous pulp material is a woven or nonwoven material, the process for the material of Greenawalt et al. (collecting fibrous pulp, pressing and drying) is inherently producing a fibrous pulp based nonwoven material. In addition, applicant argued that the material of Greenawalt et al. does not have an appropriate elasticity and flexibility to ensure valid sealing as well as excellent operability and easy handling when used for topical hemostatic.

However, this limitation has not been claimed in the current invention. Thus, the argument is moot.

Applicant also argued that the material of Greenawalt et al. utilizes organic solvent (non-aqueous solvent) while the current application utilizes an aqueous saline or buffer solution. Claim 6 and its dependents disclose a limitation of "a solution containing thrombin". Since Greenawalt et al. teach a limitation of "a solution containing thrombin" in Example 5 (column 11), the reference anticipates the claims. Therefore, the argument is found not persuasive. However, it is noted that the newly added claim 10 and its dependents disclose a limitation of "a saline solution of thrombin".

Finally, applicant acknowledged that the product of Greenawalt et al. appears to be quite similar to a hemostatic sponge of the current invention, but with poor results. This argument is merely the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See M.P.E.P. § 2129 and § 2144.03 for a discussion of admissions as prior art. Counsel's arguments cannot take the place of objective evidence. *In re Schulze*, 145 USPQ 716 (CCPA 1965); *In re Cole*, 140 USPQ 230 (CCPA 1964); and especially *In re Langer*, 183 USPQ 288 (CCPA 1974). See M.P.E.P. § 716.01(c) for examples of attorney statements that are not evidence and that must be supported by an appropriate affidavit or declaration. Most significantly applicant is advised that this kind of argument may overcome obviousness-type rejection (35 U.S.C.§103), but cannot overcome the rejection under 35 U.S.C.§102.

Nevertheless, due to the amendment, the rejection under 35 U.S.C.§102 in the previous office action is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "lyophilizing," in claim 10 does not clearly point out what subject matter this term intends to claim. It does not specify what to lyophilize. It is not clear whether the saline solution of thrombin is optionally lyophilized, or the subject matter to be lyophilized being the nonwoven fabric.

The term "unsafe" in claim 10 is a relative term which renders the claim indefinite. The term "unsafe" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clearly defined what would be "unsafe" to a living body. Furthermore, without knowing "a living body", it is not clear what would be safe or unsafe.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Greenawalt et al. (U.S. Patent 6,056,970; issued on May 2, 2000).

Claims 1-15 are drawn to a bioabsorbable synthetic nonwoven fabric holding thrombin (claim 1); a limitation to a material for the bioabsorbable synthetic nonwoven fabric is selected from the group consisting of polyglycolic acid, polylactic acid, and a copolymer of glycolic acid and lactic acid (claim 2); the material of claim 2 being polyglycolic acid (claim 3); thrombin of claim 1 being derived from human blood or a recombinant human thrombin produced by a recombinant DNA technique (claim 4); a hemostatic that uses the bioabsorbable synthetic nonwoven fabric of claim 1 (claim 5); a process of preparing the bioabsorbable synthetic nonwoven fabric holding thrombin by the steps of immersing a bioabsorbable synthetic nonwoven fabric into a solution containing thrombin and lyophilizing the obtained nonwoven fabric (claim 6); a limitation to a material for the bioabsorbable synthetic nonwoven fabric is selected from the group consisting of polyglycolic acid, polylactic acid, and a copolymer of glycolic acid and lactic acid (claim 7); the material of claim 2 being polyglycolic acid (claim 8); thrombin of claim 1 being derived from human blood or a recombinant human thrombin produced by a recombinant DNA technique (claim 9); a bioabsorbable synthetic non-woven fabric holding a hemostatic-effective amount of thrombin (claim 10); a limitation to a material for the bioabsorbable synthetic nonwoven fabric is selected from the group consisting of polyglycolic acid, polylactic acid, and a copolymer of glycolic acid and lactic acid (claim 11); the material of claim 11 being polyglycolic acid (claim 12); thrombin being derived

from human blood or a recombinant human thrombin produced by a recombinant DNA technique (claims 13-15).

Greenawalt et al. teach a composition comprising hemostatic compounds and bioabsorbable polymers. Greenawalt et al. teach that a hemostatic compound is thrombin and the bioabsorbable polymers are polyglycolide (polyglycolic acid), polylactide (polylactic acid) and copolymers thereof (column 2, lines 34-61; claims 1-9).

Greenawalt et al. also teach thrombin is derived from human plasma or synthetic forms produce by recombinant DNA technology (column 3, lines 52-64; claims 4 and 9).

Greenawalt et al. also teach the bioabsorbable fabric containing thrombin is made by mixing thrombin and bioabsorbable polymers in organic solvent and drying (lyophilizing) the combination (column 5, lines 5-11 and 29-46; claims 6-8).

Claim 10 is product-by-process claims; claims 11-16 depend from said claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the

product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Therefore, the limitation of process steps in claim 10 and its dependents is not considered as structural limitation to the product of the current invention.

Although Greenawalt et al. do not particularly disclose their product having sufficient elasticity and flexibility, since the product of Greenawalt et al. is made of the same material as the instant invention (that is polyglycolic acid, polylactic acid,

combination thereof), the product of Greenawalt et al. possesses the same property as the product of the current application.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greenawalt et al. (supra).

Claim 16 is drawn to a limitation to the fabric formed by freezing prior to lyophilizing.

Greenawalt et al. teach lyophilizing a fibrous pulp forming fabric (see above).

Although Greenawalt et al. do not particularly teach a step of freezing prior to lyophilizing the product, it would have been obvious for the person of ordinary skill in the art at the time the invention was made to freeze the product prior to lyophilization because it is well known in the art that lyophilization would typically require freezing of the material or simply lyophilization is known as freeze-drying as evidenced by Menyhart (Lyophilization: Freeze-drying).

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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